cross-section.

27. The apparatus of claim 1, where the anchoring members have a top portion and the top portion is substantially flat.

REMARKS

Claims 1-23 are pending in the outstanding Office Action. Claims 3-6, 12-21 and 23 have been canceled by this Response and Amendment. All remaining claims, claims 1-2, 7-11 and 22 stand rejected for the reasons given in the outstanding Office Action. In response, claims 1-2, 7-11 and 22 have been amended and claims 24-27 have been added. No new matter is added by these amendments. Support for these amendments and new claims can be found at page 11, lines 11-22, page 15, line 21 to page 16, line 10, and page 17, lines 6-14, among other places. Entry of these amendments are hereby requested.

With Respect to the Restriction Requirement, Paragraphs 1-3 of the Outstanding Office Action:

Claims 1-23 have been subjected to a restriction requirement. For the reasons given in the outstanding Office Action at paragraphs 1-3, claims 3-6, 12-21 and 23 have been withdrawn by the Patent and Trademark Office. The Applicants acknowledge the withdrawal and have canceled the withdrawn claims by this Response and Amendment. The Applicants request that the Patent and Trademark Office consider rejoining any of claims 3-6, 12-21 and 23 as appropriate if allowable subject matter is found.

With respect to the Rejections under 35 U.S.C. §102, Paragraphs 4-5 of the Outstanding Office Action:

Claims 1-2, 10-11 and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by United States Patent 5,267,960 to Hayman et al. for the reasons given in paragraphs 4-5 of the outstanding Office Action. The '960 Patent discloses a device for installing a catheter in a patient's body for use in delivery of a radioactive source to and from the site of a tumor. The '960 device has a closed distal end which is necessary for the '960 device to function. This aspect of the '960 device is described at numerous places throughout

the '960 disclosure, including the following places [emphasis added]:

> It is also an object of the present invention to provide a catheter which forms a **closed channel** extending from a location outside of the body to a treatment site inside the body which prevents the introduction of foreign matter into the body that cause infection while still providing treatment access to the treatment site by means of a dedicated sterile channel. [col. 2, lines 29-35]
>
> Still a further object of the present invention is to provide different methods of using the catheter to treat, for example, tumors..., wherein the **closed sterile channel,** formed by the catheter, is employed to deliver treatment materials.... [col. 2, lines 42-46]
>
> Additionally, because the catheter is a **closed system catheter**, no foreign matter catheter the body through the catheter... [col. 3, lines 2-5]
>
> With a proximal end of the inner tubular member extending out of the body and the **distal end closed**, a **closed channel** is formed which **terminates at the distal end** of the inner tubular member positioned at the treatment site. This **closed channel** thus provides a sterile route by which treatment material, for example radioactive material, can be guided, in a dedicated manner, precisely and accurately to the treatment site. [col. 3, lines 51-58]
>
> To maintain a closed system, the distal end of the inner tubular member is **sealed** upstream of the anchor. [col. 4, lines 12-13]
>
> A distal end of the inner tubular member 13, generally indicated at A, is **closed**, for example, by a **permanent plug**, 35 and provided with an anchor 19 for precisely attaching the distal end A of the catheter 11 at a desired treatment site within a body.... The **permanent plug** 35 seals the distal end of the inner tubular member 13 upstream of the detachable screw plug 33. [col. 5, lines 29-39]

By contrast, the present invention includes a flexible, elongated, hollow tubular inner lumen which has a bore extending the entire length from proximal end to distal end. This bore allows the passage of liquids or other devices into the passageway. For example, this aspect of the present invention is disclosed at page 11, lines 11-16, below, and shown in Figures 1 and 3-13 among other places [emphasis added]:

> As shown in FIGS. 1-4, in one variation of the deployment means 30, the deployment means 30 comprises a flexible, elongated, hollow tubular inner lumen 36

having a proximal end 38, a distal end 40, and **an elongated bore 42 which extends between the proximal end 38 and the distal end 40.** The inner lumen also has an inner wall 44. Because the inner lumen 36 is hollow, this enables liquids to be transported through the inner lumen to the passageway site. In addition, it enables devices, such as a transducer, to be inserted and used at the site.

Claim 1 has been amended in order to more clearly distinguish the present invention over the device disclosed in the '960 Patent. The Applicants believe that this difference alone is sufficient to overcome the rejection of claims 1-2, 10-11 and 22 under 35 U.S.C. §102(b).

Additionally, the arms of the device disclosed in the '960 Patent which secure the device in the passageway are attached to a detachable screw plug or to the closed end of the inner tubular member. This relationship is disclosed as follows, and shown Figures 1-3 [emphasis added].

A distal end of the inner tubular member 13, generally indicated at A, is closed, for example, by a permanent plug, 35 and provided with an anchor 19 for precisely attaching the distal end A of the catheter 11 at a desired treatment site within a body. **One end of each of the arms 21 is attached to the distal end A of the inner tubular member 13 by, for example, a detachable screw plug 33. Alternatively, the one end of each of the arms is connected directly to the closed distal end A of the catheter.** The permanent plug 35 seals the distal end of the inner tubular member 13 upstream of the detachable screw plug 33. [col. 5, lines 29-39]

By contrast, the anchoring members of the present invention are attached directly to the wall of the inner lumen. For example, this aspect of the present invention is disclosed at page 17, lines 6-14, below, and shown in Figures 2a and 2b among other places [emphasis added]:

If the inner lumen 36 is made of a polymeric material, the anchoring members may be attached to the deployment means by mounting the anchoring members **within the wall of the deployment means.** FIG. 2a shows an enlarged cross-sectional view taken along lines 2-2 of FIG. 1, wherein the first end portions 58 of the anchoring members 56 are mounted **within the inner wall 44 of the inner lumen 36 at the distal end 40 of the inner lumen 36.** This type of attachment of the anchoring members provides a strong and stable attachment. FIG. 2b shows an alternate variation of the enlarged transverse cross-sectional view of FIG. 2a, wherein the first end

portions 58 of the anchoring members 56 are coupled **to the surface of the inner wall 44 of the inner lumen 36 at the distal end 40** of the inner lumen 36.

Claim 1 has been amended in order to more clearly distinguish the present invention over the device disclosed in the '960 Patent. The Applicants also believe that this difference alone is sufficient to overcome the rejection of claims 1-2, 10-11 and 22 under 35 U.S.C. §102(b).

Additionally, the arms of the device disclosed in the '960 Patent which secure the device in the passageway have barbs at the end of the arms to pierce the body tissue of the passageway, thereby securing the '960 catheter in the passageway. In fact, the detachable screw plug of the '960 catheter requires that the arms be anchored in the wall rather than against the inner surface of the wall in order to allow the screw plug to be detached from the catheter. This aspect of the device disclosed in the '960 Patent is disclosed at numerous place in the '960 Patent, including the following passages [emphasis added].

> As the inner tubular member is pulled back, the bent-back **tissue penetrating end of the anchor arm** is driven into the surrounding tissue, much like a fish hook, to anchor the distal end of the catheter at a desired treatment site. [col. 2, lines 44-48]

> The anchor comprises at least one, spring-loaded, hook-shaped arm **which forms a barb** when released from the storage space for **penetrating surrounding tissue**. [col. 3, lines 26-29]

> According to yet a further embodiment of the present invention, the anchor comprises two bent-back, spring-loaded, stainless steel wire arms **which each form a barb**. [col. 4, line 21-24]

> The other end of the [sic] each of the arms 21 forms **tissue penetrating end** 23 which is bent-back away from the distal end A of the inner tubular member 13 to **form a barb which penetrates** about 1 mm into the tissue when the anchor 19 is deployed as shown in FIG 1C. [col. 5, lines 55-59]

> Relative slidable movement between the inner and outer tubular member 13, 15, as illustrated in FIG 1B, frees the **tissue penetrating ends** 23 of the pair of spring-loaded, hook-shaped arms 21 from the storage. This permits the arms 21 of the anchor 19 to swing out and way [sic] from the distal end A of the inner tubular member 15 and

> **penetrate tissue** at a treatment site to anchor the catheter 11 as shown in FIG. 1C and as will be further described hereinafter with reference to FIG 3A. [col. 6, lines 1-9]

By contrast, the present invention was designed to minimize the possibility of tissue damage to the wall of the passageway, such as occurs by piercing the wall of the passageway. The present catheter is held in place by resilient anchoring members which deform to engage the inner surface of the wall of the passageway, rather than piercing the wall of the passageway. A considerable amount of disclosure in the present application is directed toward this aspect of the present invention. See for example, page 12, line 12 through page 16, line 10. This aspect of the present invention can be particularly appreciated from the following passages, and from Figures 1, 3 and 4, among other places [emphasis added].

> The use of pseudoelastic material for the anchoring members of the present invention may **prevent excess force on the wall of the mammalian passageway** due to the nature of the stress-strain plateau. [page 14, line 21 to page 15, line 1]

> The shape of the anchoring members, especially the second end portion, may vary depending on the **amount of contact that is desired by the anchoring members against the passageway surface and depending on the curvature of the passageway surface**. [page 15, line 21 to page 16, line 1]

> It is desirable that the anchoring members, especially **the second end portion of the anchoring members, be designed to provide a greater surface area of contact against the passageway, which, in turn, provides a greater anchoring force**. [page 16, lines 7-10]

Claim 1 has been amended in order to more clearly distinguish the present invention over the device disclosed in the '960 Patent. The Applicants also believe that this difference alone is sufficient to overcome the rejection of claims 1-2, 10-11 and 22 under 35 U.S.C. §102(b).

For each of the reasons given above, claim 1 is believed to be patentable over the '960 Patent. Claims 2, 10-11 and 22 depend on claim 1. Therefore, withdrawal of the rejection under 35 U.S.C. §102(b) is hereby requested.

With respect to the Rejections under 35 U.S.C. §103, Paragraphs 6-9 of the Outstanding

Office Action:

Claims 7-9 stand rejected under 35 U.S.C. §103(a) for the reasons given in paragraphs 6-9 of the outstanding Office Action. Each of these claims are dependent on claim 1. For the reasons given above, claim 1 is believed to be patentable. Therefore, these rejections under 35 U.S.C. §103 are now believed to be moot and withdrawal of these rejections is hereby requested.

CONCLUSION

For the reasons given above, the Applicant believes that all pending claims, claims 1-2, 7-11, 22 and 24-27 are patentable and an allowance of these claims is earnestly solicited. If, however, there are any questions that can be addressed by telephone with the Applicant's representative, the Examiner is requested to contact the undersigned.

Please deduct all fees associated with this communication, including the fees for the added claims, from Deposit Account No. 19-2090.

Respectfully submitted,
SHELDON & MAK

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